REMARKS

The Office Action has been carefully reviewed. No claim is allowed. Claims 1, 2, 4-9, and 18-52 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

The undersigned has not yet been able to locate copies of references AN, AT and BG. If the references are found, copies will be submitted in a supplemental response.

Non-elected claims 10-17, and 62-94 are now cancelled without prejudice to the filing of a divisional application thereon.

Claim 3 has been rejected under 35 U.S.C. §101 as claiming the same invention as that of claim 29 of prior U.S. patent 6,214,584. This rejection is made moot by the cancellation of rejected claim 3.

Claims 53-61 have been rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1-9 of prior U.S. patent 6,207,641. This rejection is also mooted by the cancellation of the rejected claims 53-61.

Claims 1, 2, 4, and 5 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27, 28, 30, and 31 of U.S. patent 6,214,584 in view of claim 29 from that same patent. Similarly, claims 1-4, 6-9, 18, 18, 21-55, and 57-61 have been

rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. patent 6,441,138, and likewise rejected over claims 1-3 of U.S. patent 6,403,079. In addition, the claims 1-9 and 18-61 have also been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. patent 6,207,641. These obviousness-type double patenting rejections are now obviated by the terminal disclaimer attached hereto.

Claim 53 and its dependent claims 54-61 have been objected to because of informalities. This objection is obviated by the cancellation of the objected claims.

Claims 18, 20, 21-52, 57, and 53-57 have been rejected under 35 U.S.C. 112, first paragraph, because the examiner finds that the specification, while being enabling for a composition comprising SEQ ID NO:6, or for derivatives thereof varying from SEQ ID NO:6 by one amino acid residue, does not reasonably provide enablement for a composition comprising any homologue of the sequence. The examiner states that the specification does not reasonably provide enablement for a composition comprising any homologue of SEQ ID NO:6 because;

(a) the specification fails to identify what regions of the disclosed protein are active in inducing interferon-γ production;

(b) the specification provides no guidance to allow a

skilled artisan to obtain functional homologues to the disclosed protein without undue experiments;

(c) the specification identifies no functional homologues; and

(d) the specification only discloses that functional homologues may be made by substituting, adding, or deleting one or more amino acids in the protein in SEQ ID NO:6, this is obvious and unhelpful.

This rejection is respectfully traversal.

The present specification discloses at page 7 that the IFN-γ production inducing protein isolated from mouse liver has the 157 residue amino acid sequence of SEQ ID NO:4, where Xaa represents methionine or threonine. On the same page, the present specification also discloses the isolation of a human IFN-γ production inducing polypeptide, also having 157 residues but with a different amino acid sequence of SEQ ID NO:6, where Xaa represents isoleucine or threonine. It is clear to those of skill in the art that the mouse IFN-γ production inducing polypeptide of SEQ ID NO:4 is a homologue of the human IFN-γ production inducing polypeptide of SEQ ID NO:6. They both have the same length, the same activity, and a mere glance at the sequences of SEQ ID NOs: 4 and 6 show high homology, which would be readily confirmed by performing an amino acid sequence alignment as is conventional in the art. Such a sequence alignment would reveal where there is sequence conservation and

where that is sequence variability/divergence. As disclosed in the Bowie et al., (1990) reference cited by the examiner, "residues that are directly involved in protein functions such as binding or catalysis will certainly be among the most conserved" (page 1306, middle of right column). Accordingly, one of skill in the art would well appreciate which residues, based on amino acid conservation in the amino acid sequence alignment, are likely to be important to protein function, whether at the binding or catalytic site, or important to maintaining the active conformation of the binding or catalytic site. Residues and regions that are not conserved would then offer the opportunity for amino acid changes such as substitutions, additions and deletions, and one of skill in the art is indeed provided with guidance in the present specification to obtain homologues as presently claimed.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Claims 18, 20, 21-52, 57, and 53-57 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

As discussed above in the enablement rejection, the

mouse IFN-γ production inducing protein of SEQ ID NO:4 is an example of a homologue and furthermore, immediately provides a genus of homologues based on the conservation or non-conservation of residues in an amino acid alignment of SEQ ID NO:4 and SEQ ID NO:6. Accordingly, the specification provides adequate written description for the rejected claims.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 18 and 20-57 have been rejected under 35 U.S.C. §112, second paragraph. The rejection as it relates to claims 53-57 is made moot by the cancellation of claims 53-57 without prejudice. The rejections as it relates to claim 18 and 20-52 is traversed for the reasons discussed above in the §112, first paragraph, rejections on "homologue".

Claim 19 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claim 19 is now amended to delete the recitation of "biologically active". However, as recited in claim 19, the fragment is also an interferon-γ production inducing polypeptide and therefore, claim 19 is not indefinite.

Claim 53 and its dependent claims 54-61 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is obviated by the cancellation of the rejected claims.

Claims 53, 56, 57, and 60 have been rejected under 35 U.S.C. §102(e) as being anticipated by U.S. patent 5,912,324. This rejection is obviated by the cancellation of rejected claims 53, 56, 57 and 60.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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